

Appl. No. : 09/706,965
Filed : November 6, 2000

REMARKS

The September 10, 2002 Office Action was based upon pending Claim 1. This Amendment amends Claim 1 and adds new Claims 12-15. Thus, after entry of this Amendment, Claims 1 and 12-15 are pending and presented for further consideration. For the reasons set forth hereinafter, Applicants respectfully request the Examiner to pass Claims 1 and 12-15 to allowance.

The specific changes to the specification and the claims are shown on a separate set of pages attached hereto and entitled **VERSION WITH MARKINGS TO SHOW CHANGES MADE**, which follows the signature page of this Amendment. On this set of pages, the insertions are underlined while the ~~deletions are struck through~~.

Priority Claim

The specification has been amended to identify the application as a continuation of Application Number 09/190,719, filed on November 12, 1998, now U.S. Patent No. 6,151,516 issued Nov. 21, 2000.

Rejections Under 35 U.S.C. §112, Second Paragraph

In the September 10, 2002 Office Action, the Examiner rejected Claim 1 asserting that the limitation "the volume" lacks antecedent basis. Claim 1 has been amended to recite "a volume." Applicants respectfully request the Examiner to withdraw the rejection under 35 U.S.C. §112, second paragraph.

Double Patenting

The Examiner provisionally rejected Claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 7 of U.S. Patent No. 6,151,516 to Kiani-Azarbayjany, et al. ('516) in view of U.S. Patent 4,883,055 to Merrick. Claim 1 was also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 5,860,919 to Kiani-Azarbayjany, et al. ('919) in view of U.S. Patent No. 4,883,055 to Merrick.

Applicants file contemporaneously with this Amendment a Terminal Disclaimer under 37 C.F.R. §1.130(b) and §1.321(c). Applicants respectfully request the Examiner to withdraw the rejection under the judicially created doctrine of obviousness-type double patenting.

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Claim Rejections Under 35 U.S.C. §102(b)

The Examiner rejected Claim 1 as being anticipated by Merrick (U.S. Patent 4,883,055) or Branstetter (U.S. Patent No. 5,007,423). As to Merrick, the Examiner asserts that Merrick discloses a pulse oximeter, which measures oxygen saturation in arterial blood, a light source emitting a plurality of wavelengths and a detector. The Examiner asserts further that Merrick discloses a finger cuff that artificially induces a blood pulse, and a signal processor. As to Branstetter, the Examiner asserts that Branstetter discloses a pulse oximeter, which measures oxygen saturation in arterial blood, a light source emitting a plurality of wavelengths, a detector and a signal processor. The Examiner asserts further that Branstetter discloses artificially inducing a blood pulse by heating.

Without any admission that the Examiner's assertions are correct, Applicants have amended Claim 1 to expedite examination and allowance of Claims 1 and 12-15. Amended Claim 1 defines a system for non-invasively monitoring concentrations of blood constituents in a living subject. The system includes a light source configured to irradiate a fleshy medium with radiation at a plurality of wavelengths, each wavelength selected for monitoring a selected one of a plurality of blood constituent concentrations, including glucose concentration. The system includes an active pulse inducement device, which causes a periodic change in a volume of blood in the fleshy medium, and an optical detector positioned to detect light which has propagated through the fleshy medium. The optical detector generates an output signal indicative of the intensity of the radiation after attenuation through the fleshy medium. A signal processor responsive to the output signal analyzes the output signal to extract portions of the signal due to optical characteristics of the blood to determine the concentration of at least one constituent within the subject's bloodstream.

Merrick does not disclose or suggest each and every limitation recited in amended Claim 1. Merrick measures only one characteristic of blood, namely, oxygen saturation in arterial blood. (Abstract.) Therefore, Merrick does not disclose or suggest a system for non-invasively monitoring concentrations of blood constituents, i.e., several blood constituents.

Accordingly, Merrick does not disclose a light source as defined in amended Claim 1. Merrick discloses "means for transmitting at least two wavelengths of light related to hemoglobin light absorption through a body member." (Claim 1.) Thus, Merrick's light source is limited for a blood constituent, namely, hemoglobin. Conversely, amended Claim 1 recites a light source

configured to irradiate a fleshy medium with radiation at a plurality of wavelengths, wherein each wavelength is selected for sensitivity to at least one of a plurality of blood constituent concentrations, including glucose concentration. Thus, the light source recited in amended Claim 1 provides for monitoring of several blood constituents, including glucose concentration.

As to the light source, the specification explains that:

- A sensor 300 has multiple light emitters 301-305 such as LED's. In the present embodiment, each LED 301-305 emits light at a different wavelength. ... [O]ne wavelength is provided for each constituent which is accounted for. (Page 12, lines 24-31.)
- [A]advantageous wavelengths for the emitters 301-305 (or to obtain with the filter wheel and signal processing) are 660 nm (good attenuation hemoglobin), 905 nm (good attenuation from oxyhemoglobin), 1270 nm (good attenuation by water, and little attenuation by other constituents) 1330-1340 nm (good attenuation due to Glucose in the area of the graph labelled A of FIG. 9, not totally obscured by the attenuation due to water), and 1050 nm (an additional point for good attenuation from Glucose). The use of two wavelengths to account for glucose attenuation provides overspecification of the equations. Overspecification of the equations discussed below increases resolution. Additional wavelengths to account for other constituents such as fats and proteins or others could also be included. For instance, an additional wavelength at 1100 nm could be added (good attenuation from proteins) and 920 nm (good attenuation from fats). Another constituent often of interest is carboxyhemoglobin. A wavelength for carboxyhemoglobin is advantageously selected at 700-730 nm. (Page 13, line 28 – Page 14, line 10.)

The claimed system having such a light source, unlike Merrick, allows monitoring glucose and other difficult to detect blood constituent concentrations. (Page 1, lines 4-7.)

For the foregoing reasons, Applicants submit the Merrick fails to disclose or to suggest each and every limitation recited in amended Claim 1. Merrick, therefore, not only fails to anticipate Claim 1, but also fails to provide any suggestion for a system that allows monitoring several blood constituents, including glucose. Applicants respectfully request the Examiner to pass amended Claim 1 to allowance.

Branstetter does not disclose or suggest each and every limitation recited in amended Claim 1. Similar to Merrick, Branstetter measures only one characteristic of blood, namely, oxygen saturation in arterial blood. (Abstract.) Therefore, Branstetter does not disclose or suggest a system for non-invasively monitoring concentrations of blood constituents, i.e., a

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plurality of blood constituents, and the comments set forth above with respect to Merrick apply equally to Branstetter.

For these reasons, Applicants submit the Branstetter fails to disclose or to suggest each and every limitation recited in amended Claim 1. Branstetter, therefore, not only fails to anticipate Claim 1, but also fails to provide any suggestion for a system that allows monitoring several blood constituents, including glucose. Applicants respectfully request the Examiner to pass amended Claim 1 to allowance.

Because Claims 12-15 depend from independent Claim 1, pursuant to 35 U.S.C. § 112, ¶ 4, they incorporate by reference all the limitations of the claim to which they refer. It is therefore submitted that Claims 12-15 are in condition for allowance at least for the reasons expressed with respect to the independent claim, and for their other inventive features. Thus, Applicants respectfully request the Examiner to allow Claims 12-15.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested.

If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

1. (Amended) A system for non-invasively monitoring concentrations of a-blood constituents ~~concentration~~ in a living subject, said system comprising:

a light source configured to irradiate a fleshy medium with ~~which emits~~ radiation at a plurality of wavelengths, each wavelength selected for attenuation sensitivity to monitoring one of at least one of a plurality of blood constituent concentrations, said plurality of blood constituent concentrations including a glucose concentration;

an active pulse inducement device which causes a periodic change in ~~the~~ a volume of blood in the fleshy medium;

an optical detector positioned to detect light which has propagated through said fleshy medium, said optical detector configured to generate an output signal indicative of the intensity of said radiation after attenuation through said fleshy medium; and

a signal processor responsive to said output signal to analyze said output signal to extract portions of said signal due to optical characteristics of said blood to determine the concentration of ~~said~~ at least one selected constituent within said subject's bloodstream.

12. (New) The system of Claim 1, wherein the active pulse inducement device causes a periodic change in the volume of blood in the fleshy medium independent of the natural flow of blood in said fleshy medium.

13. (New) The system of Claim 1, wherein the active pulse inducement device causes a periodic change in the volume of blood in the fleshy medium in conjunction with the natural flow of blood in said fleshy medium.

14. (New) The system of Claim 1, further comprising a receptacle which receives said fleshy medium, said receptacle further having an inflatable bladder.

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15. (New) The system of Claim 1, further comprising a receptacle which receives said fleshy medium, said receptacle further comprising a temperature variation element, said temperature variation element cyclicly varying the temperature of said fleshy medium in order to induce a change in the flow of blood in said fleshy medium.